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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,768	07/20/2006	Andreas Meudt	2004DE302	7994
38263 7590 05/21/2008				
PROPAT, L.L.C.				
425-C SOUTH SHARON AMITY ROAD				
CHARLOTTE, NC 28211-2841				
EXAMINER				
MABRY, JOHN				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
05/21/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/586,768

Applicant(s)

MEUDT ET AL.

Examiner

John Mabry, PhD

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/27/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/88)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Examiner's Response

Applicant's response on March 27, 2008 filed in response to the Office Action dated December 27, 2008 has been received and duly noted. In view of this response, the status of the rejections/objections of record are as follows:

Status of the Claims

Claim 12 is new.

Claims 1-12 are pending and rejected.

35 USC § 112 Rejection(s)

The 112-2nd rejection of claims 2-4 and 10 regarding structure of Formula I and its valency have been overcome in view of Applicants amending the claims.

The 112-2nd rejection of claims 2-4 and 10 regarding the term "and/or" have not been overcome in view of Applicants amendment to the claims. This issue remains in claim 10.

The 112-1st rejection of claims 1-11 regarding the written description of the terms aryl and heteroaryl have not been overcome in view of Applicants unpersuasive arguments. See Examiner's rejection below.

The 112-1st rejection of claims 1-11 regarding the integer x being 4 and 5 and R' being cyclic C3-C16 radical, aryl and heteroaryl have been overcome in view of Applicants amending the claims.

An action on the merits of claims 1-12 is contained herein below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have argued that the term "aryl and heteroaryl" are extremely well-established terms of art. This is not persuasive because there are inconsistent and differing uses of the word "aryl and heteroaryl" in the art. The widely used "Condensed Chemical Dictionary" states that the term heteroaryl means - designating a closed-ring structure, usually of either 5 or 6 members, in which one or more of the atoms in the ring is replaced with sulfur or nitrogen (see page 566 - the term "heteroaromatic" references the term "heterocyclic", so Examiner will use the definition of heterocyclic with the term heteroaryl). The widely used textbook "Organic Chemistry" by Fessenden says on page 451 that the compounds must be aromatic but that any and all atoms in the ring may be selected from the entire periodic table, not just selected from sulfur or

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nitrogen. The less widely used textbook "Introduction to Organic Chemistry" by *Streitwieser* on page 1061 defines "heterocycles" as both aromatic and nonaromatic. It further implies that the nitrogen, oxygen and sulfur atoms are commonly meant and that any size ring falls under the rubric of the word. A similar rationale can be used for the term "aryl".

The Board of Patent Appeals and Interferences held, and the court affirmed *In re* Hawkins 179 USPQ 421 that "It must also be noted that the claim terminology is so broad that it does not even require that the heterocyclic group contain a carbon atom. Heterocyclic ring systems containing phosphorus, boron, silicon and other elements in addition to nitrogen and oxygen without the inclusion of carbon atoms are well-known and could not be expected to produce compounds having the properties herein claimed."

Additionally, claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no evidence/written description in the specification for R of Formulas II and III is aryl or heteroaryl. Additionally, there are no examples or reduction to practice of said groups.

The methodology for determining adequacy of written description to convey that Applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention

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is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement; (Federal Register/Vol 66. No. 4, Friday, January 5, 2001;11 Methodology for Determining Adequacy of Written Description (3.)).

Claim Coverage

The instant application claims a process for preparing a) nitriles of the formula II and b) isonitriles of the formula III.

Applicants' Reduction to Practice

According to the Specification at the time of filing, Examiner has concluded that Applicant was not in possession of the claimed invention.

Level of Skill and Knowledge in the Art

The ordinary artisan is highly skilled, e.g. a masters or PhD in the chemical sciences. The level of skill in the art is high because of experimentation may be expansive and unpredictable.

According to the MPEP §2163 I. A. "the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has been described with sufficient particularity such that one skilled in the art would

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recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the area or known to one of ordinary skill in the art." The MPEP states in §2163 II 3 ii) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see I) (A), above), reduction to drawings (see I)(B), above), or by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see I)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43, USPQ2d at 1406."

As discussed above, the R groups being aryl and heteroaryl is not defined or contained in the Specific and the art recognized definitions are shown to be inconsistent.

According to the MPEP §2163.02 Standard for Determining Compliance with the Written Description Requirement,

"The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or

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she invented what is claimed". *In re Gosteli*, 872, F.2d 1008 1012, 10 USPQ2d 1614, 1618 (Fed. Cir.1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter". *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375 217 USPQ 1089, 1096 (Fed. Cir. 1983))."

Working Examples and Guidance Provided

The Specification does not demonstrate any support for R being anything chemical moiety other than phenyl and L-phenylalanine methyl ester. There are no working examples of claimed process wherein any heteroaryl group is used. The Specification does not even meet the minimum art recognized experimental standards. In the art, the claimed process of preparing only uses phenyl groups. However, there are no examples using art recognized where R is any chemical moiety other than phenyl in the instant applicant. There is no data is provided in the Specification that teaches the full claimed scope of how to make the products II and III.

State of the Art and Analysis of the Issues

The nature of the invention is the process of preparing compounds II and III where R is all aryl and heteroaryl groups (which is not defined in the Specification); the state of the prior art is not well developed and is highly unpredictable. There are no teachings of how to make the claimed compounds where R is heteroaryl. There is insufficient disclosure to reasonably predict that the process can be used and is compatible with any heteroaryl substituent. This is merely an unsubstantiated assertion with no evidence to support. With the lack of examples and guidance as discussed above, one of ordinary skill in the art would reasonably have considered that at the time the application was filed, that the Applicant was not in possession of the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, PhD, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry, PhD/
Examiner
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/Rita J. Desai/
Primary Examiner, Art Unit 1625